

Testimony of
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on

MEDICARE COVERAGE OF SELF-ADMINISTERED DRUGS

before the

HOUSE COMMERCE HEALTH AND ENVIRONMENT SUBCOMMITTEE

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Chairman Bilirakis, Congressman Brown, distinguished Subcommittee members, thank you for inviting us to discuss Medicare coverage for self-administered drugs. The current situation provides a compelling example of why we must modernize Medicare with an affordable, comprehensive, outpatient prescription drug benefit available to all beneficiaries.

Medicare coverage for pharmaceuticals is now severely restricted outside of hospitals and nursing facilities. Congress has created only a limited number of exceptions, each spelled out in the law. One exception is for drugs that cannot be self-administered. Section 1861 (s)(2)(A) of the statute says Medicare may pay for drugs "which cannot, as determined in accordance with regulations, be self-administered" when furnished "as an incident to a physician's professional services, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills."

Medicare's longstanding policy for coverage under this exception has addressed only whether a drug can be self-administered, not whether an individual patient can self-administer the drug. And Congress has not provided an explicit exception for those who cannot self-administer drugs that generally are self-administered.

The shortcomings of such a policy become clearer every day with dramatic new advances in drug therapies. Medicaid and most private insurers pay for all prescription drugs, regardless of whether they are self-administered. The current policy is most troubling for conditions such as multiple sclerosis, where some patients sometimes can administer their drugs and others cannot. It is enough of a burden to cope with the effects of such a disease without the worry of paying for expensive drugs. We all agree that the current limitations on Medicare coverage for self-administered drugs leave beneficiaries without the medications they need. However, regulatory action to create limited exceptions allowing coverage for only some beneficiaries may not be the best solution to this problem.

Our clinicians at HCFA are concerned that creating such a narrow exception to the ban on

Medicare coverage for outpatient drugs could create an ethical dilemma for compassionate physicians when caring for patients who can self-administer drugs but cannot afford the drugs they need. This approach could compound the current inequities in coverage, and may also create program integrity problems.

This issue is, in fact, a small part of a much larger problem for which patchwork solutions will not suffice. As many Medicare beneficiaries lack drug coverage today as senior citizens lacked hospital coverage when Medicare was created. All beneficiaries, regardless of health or income, need access to an affordable, comprehensive outpatient drug benefit, as has been proposed by the President.

BACKGROUND

Like many specific coverage policies in Medicare's history, determination of whether a specific drug could be self-administered has been left up to the medical directors of each claims processing contractor. Instructions to Medicare claims processing contractors on this issue have been provided through the Medicare Carrier Manual and were updated in 1995. Those instructions state that drugs may be covered only if they "are of the type that cannot be self-administered."

The question of whether a drug could be "self-administered" was self-evident when Medicare was created in 1965. A pill was self-administered, most injections except for insulin were not, so regulations defining "self-administered" were not promulgated. But now, dramatic advances in drug therapies have changed the medical landscape. Cancer drugs, for example, that had been available only as injections have become available in pill form.

Congress recognized some of these changes in technology in the Omnibus Budget Reconciliation Act of 1993 by authorizing Medicare coverage for certain oral anticancer drugs that contain the same active ingredient as an injectable drug that would be administered by a physician. The law also allowed for coverage of self-administered anti-emetic agents necessary for proper absorption of oral anticancer drugs covered under this provision. And it provided for coverage of clotting factors that hemophiliacs self-administer to control their condition.

Congress, however, has not created exceptions in the law to accommodate other compelling situations. Pharmaceutical advances are allowing more types of patients with different types of diseases to be successfully taught to administer drugs they need themselves. But some of these new agents are for conditions, such as multiple sclerosis, that create an unfortunate dilemma. Many of these patients can self-administer drugs. But others, especially those in later stages of the disease, are so debilitated that they cannot administer the drugs themselves.

We issued a memorandum in August 1997 clarifying the guidance in our carrier manual to emphasize that Medicare claims processing contractors may cover generally self-administered drugs when a provider is administering the drug in order to teach a patient how to self-administer. We did this to encourage more coverage in these situations. The memorandum also reiterated the long-standing policy that an "individual patient's mental or physical ability to administer any drug" may not be taken into consideration.

Because of continuing concern over this issue, we had planned to publish a proposal in the *Federal Register* exploring options and requesting public comments on ways to define "self-

administered" through regulation. One option would have been to possibly expand coverage by taking individual patient conditions into account. Unfortunately, some observers misinterpreted our plans for a proposal in the *Federal Register* as an effort to further restrict coverage.

This series of events led to inclusion of language in the Appropriations Act of 2000 in which Congress barred use of HCFA funds to carry out the transmittal of the August 1997 memo. The appropriations language also prohibited us from promulgating "any regulation or other transmittal or policy directive that has the effect of imposing (or clarifying the imposition of) a restriction on the coverage of injectable drugs under section 1861(s)(2) of the Social Security Act beyond the restrictions applied before the date of such transmittal."

We therefore postponed our proposal to solicit public comments on options in the Federal Register to avoid the appearance that we are attempting to restrict coverage in violation of the appropriations language. We have also suspended our 1997 memorandum and, as required by the law, alerted our contractors that current guidance on this matter is limited to instructions issued to them before the 1997 memorandum. We also are scheduling town hall meetings, as directed by Congress, to allow all interested parties to air concerns about the current situation and discuss available options. The first is set for May 18 in Baltimore.

We all agree that the current situation is not acceptable. The best solution is to provide all beneficiaries with access to affordable and comprehensive coverage for outpatient prescription drugs.

Need for Comprehensive Drug Benefit

Prescription drugs are as essential to modern medicine today as hospital care was when Medicare was created. Yet as many beneficiaries lack drug coverage today as senior citizens lacked hospital coverage then. Three out of five lack dependable coverage. Only half of beneficiaries have year-round coverage, and one third have no coverage at all.

Beneficiaries without drug coverage must pay for essential medicines fully out of their own pockets, and are forced to pay full retail prices because they do not get the generous discounts offered to insurers and other large purchasers. The result is that many go without the medicines they need to keep them healthy and out of the hospital.

This year more than half of Medicare beneficiaries will use prescription drugs costing \$500 or more, and 38 percent will spend more than \$1000. Each year, about 85 percent of Medicare beneficiaries fill at least one prescription. About half of the beneficiaries without coverage have incomes above 150 percent of poverty (above \$17,000 for an elderly couple). Analysis by the National Economic Council shows that middle-income beneficiaries without prescription drug coverage purchase 20 percent fewer drugs but pay about 75 percent more out-of-pocket than those with drug coverage.

This situation is worse for the 10 million Medicare beneficiaries who live in rural areas. Nearly half of these beneficiaries have absolutely no drug coverage. They have less access to employer-based retiree health insurance because of the job structure in rural areas. And three-quarters of rural beneficiaries do not have access to Medicare+Choice plans and the drug coverage that many of these plans provide.

No one would design Medicare today without including broad coverage for prescription drugs. The private sector now includes outpatient drug coverage as a standard benefit in almost all policies. Further, all plans in the Federal Employees Health Benefits Program are required to offer a prescription drug benefit. And prescription drugs are particularly important for seniors and disabled Americans, who often take several drugs to treat multiple conditions. All across the country, Medicare beneficiaries are suffering physical and financial harm because they lack substantive prescription drug coverage.

The President has proposed a comprehensive Medicare reform plan that includes a voluntary, affordable, accessible, competitive, efficient, quality drug benefit that will be available to all beneficiaries. The President's plan dedicates over half of the on-budget surplus to Medicare and extends the life of the Medicare Trust Fund to at least 2025. It also improves preventive benefits, enhances competition and use of private sector purchasing tools, and strengthens program management and accountability.

Key Principles

The President has identified key principles that a Medicare drug benefit must meet.

- **It must be a voluntary benefit accessible to all beneficiaries.** Since access is a problem for beneficiaries of all incomes, ages, and areas, we must not limit a Medicare benefit to a targeted group.
- **It must be affordable to beneficiaries and the program.** We must provide assistance so almost all beneficiaries participate. Otherwise, primarily those with high drug costs would enroll and the benefit would become unaffordable. And beneficiaries must have meaningful protection against excessive out-of-pocket costs.
- **It must be competitive and have efficient administration.** Beneficiaries must have bargaining power in the market place. And we must integrate the benefit into Medicare but use the private sector to deliver it.
- **It must ensure access to needed medications and encourage high-quality care.** Beneficiaries must have a defined benefit providing access to the medications that their physicians deem to be medically necessary, and they must have the assurance of minimum quality standards, including protections against medication errors.
- **It must be consistent with broader reform.** The drug benefit should be a consistent part of a larger plan to strengthen and modernize Medicare.

The President's plan meets these principles.

- Beneficiaries will have access to an optional drug benefit through either traditional Medicare or Medicare managed care plans. Those with retiree coverage can keep it.
- Premiums will be affordable, with extra assistance for those with low-incomes.
- There will be no price controls or new bureaucracy; instead, the new benefit will be offered through private pharmacy benefit managers who can efficiently negotiate fair

prices. All qualified pharmacies will be allowed to participate.

- Beneficiaries can get all drugs prescribed by their physicians from private benefit managers who meet minimum quality standards.

CONCLUSION

The need for an affordable, comprehensive, outpatient prescription drug benefit in Medicare is clear. The program's current coverage restrictions leave many beneficiaries without the coverage they need.

We want to expand coverage to all beneficiaries, not further restrict coverage. Patchwork solutions and limited exceptions cannot address a problem of this magnitude. There is broad consensus that the Medicare program must cover prescription drugs. Mr. Chairman, the opportunity is before us. The time to act is now.

We look forward to working with you further on this critical issue. I thank you for holding this hearing, and I am happy to answer your questions.

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